K110773(1/3)

SECTION 5

JUN - 2 2011

510(k) SUMMARY

Summary of Safety and Effectiveness information

Tornier Insite™ FT Suture Anchors

Regulatory authority: Safe Medical Devices Act of 1990, 21 CRF 807.92

1) **Device name**

Device name:	**Tornier Insite™ FT Suture Anchors**
Common name:	Fastener, fixation, non-degradable, soft tissue
Classification name:	Smooth or threaded metallic bone fixation fastener
Classification number:	888.3040 - Smooth or threaded metallic bone fixation fastener.

Product code: MBI

2) **Submitter**

Tornier Inc.
7701 France Avenue South; Suite 600
Edina, MN 55435
Registration Number: 9100540

3) **Company contact**

Brahim Hadri
Sr. Regulatory affairs Specialist
100 Cummings Center, Suite 444C,
Beverly, MA 01915, U.S.A
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4) **Classification**

Device class:	Class II
Classification panel:	Orthopedic
Product code:	MBI

5) **Legally Marketed Device to which Equivalence is Claimed:**

The **Tornier Insite™ FT Suture Anchor** is substantially equivalent in Intended Use and Fundamental Scientific Technology to the following legally marketed devices in commercial distribution:

- TORNIER, INC., INSITE SUTURE ANCHORS **K083268**
- TORNIER, PITON FIXATION IMPLANT SYSTEM **K091870**
- SMITH & NEPHEW INC., ENDOSCOPY DIVISION BIORAPTOR 2.3 PK SUTURE ANCHOR **K071586**

6) **Device Description**

The **Tornier Insite™ FT Suture Anchor** consists of a bone implant device intended for the fixation of soft tissue to bone. This device is a fully threaded anchor that is available in three sizes (4.5mm, 5.5mm, and 6.5mm) and two materials (PEEK-OPTIMA® and Titanium) for use in a range of fixation applications. The device is assembled pre-loaded onto the insertion device with attached USP size #2 UHMWPE braided sutures.

The **Tornier Insite™ FT Suture Anchor** is individually packaged and sterilized through ethylene oxide (EO) using appropriate standards and guidelines.

7) **Materials**

The **Tornier Insite™ FT Suture Anchor** is available in two materials: PEEK-OPTIMA® (ASTM F-2026) and Titanium (ASTM F-136) with attached USP size #2 UHMWPE braided sutures.

8) **Indications for Use**

The **Tornier Insite™ FT Suture Anchors** are intended for fixation of soft tissue to bone.

The **Tornier Insite™ FT Suture Anchors** are intended for use in the following applications:

1. **Shoulder:** Rotator Cuff, Bankart and SLAP lesion repair, Biceps tenodesis, Acromio-Clavicular separation and Deltoid repair, Capsular shift and Capsulolabral reconstruction.

2. **Foot/Ankle:** Lateral and Medial stabilization, Achilles tendon and Metatarsal ligament repair, Hallux Valgus and Midfoot reconstruction.

3. **Knee:** Medial collateral and Lateral collateral ligament repair, Patellar tendon and Posterior oblique ligament repair, Illiotibial band tenodesis.

4. **Hand/Wrist:** Scapholunate ligament, Radial collateral ligament and Ulnar collateral ligament reconstruction.

5. **Elbow:** Biceps tendon reattachment, Tennis elbow repair, Ulnar and Radial collateral ligament reconstruction.

9) **Summary of Technologies**

The technological characteristics (material, design, sizing, indications, sterilization, and fixation strength) of the **Tornier Insite™ FT Suture Anchors** are similar or identical to the cited predicate devices.

10) **Nonclinical Testing**

Non-clinical laboratory testing was performed to verify the fixation strength of the **Tornier Insite™ FT Suture Anchors** in mechanical insertion and pullout testing as compared to the predicate devices for specific indications for use. The efficacy of the **Tornier Insite™ FT Suture Anchors** were compared to the above cited predicates device. The test results indicate that the **Tornier Insite™ FT Suture Anchors** provide equivalent fixation strength to the above cited predicate devices and would be functional within their intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Tornier, Inc.
% Mr. Brahim Hadri
Senior Regulatory Affairs Specialist
100 Cummings Center, Suite 444C
Beverly, Massachusetts 01915

JUN - 2 2011

Re: K110773
Trade/Device Name: Tornier Insite™ FT Suture Anchor
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: MBI
Dated: April 26, 2011
Received: April 27, 2011

Dear Mr. Hadri:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Eric S. Keith

for Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K110773 (1/1)

INDICATIONS FOR USE

510(k) Number (if known):

Device Name: **Tornier Insite™ FT Suture Anchor**

Indications for Use

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5. **Elbow:** Biceps tendon reattachment, Tennis elbow repair, Ulnar and Radial collateral ligament reconstruction.

- Prescription Use ___X___ AND/OR Over-The-Counter Use___

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Erin L. Keith

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices